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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|------------------------------|------------------|
| 10/015,778 | 12/17/2001 | Douglas D. Sjostrom | 02-35-0385 / 00167-456001 | 4406 |
| 7590 | 10/28/2004 | | EXAMINER | NGUYEN, VI X |
| JOEL R. PETROW Smith & Nephew, Inc. 1450 Brooks Road Memphis, TN 38116 | | | ART UNIT | PAPER NUMBER |
| | | | 3731 | |

DATE MAILED: 10/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-----------------|----------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/015,778 | SJOSTROM, DOUGLAS D. |
| | Examiner | Art Unit |
| | Victor X Nguyen | 3731 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 19 August 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 18-60 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 18-60 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/19/2004 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 18-24,25-29,33-34,43,45,50-51 and 60 are rejected under 35 U.S.C. 102(b) as being anticipated by Baehr et al (U.S. 3,906,954).

Baehr et al disclose in fig. 1, col. 2, lines 48-54, col. 3, lines 1-7 and col. 4, lines 29-32, a surgical cutting instrument having the limitations of claims 25,42 and 59, including: a cutting instrument (10); an outer member (20) has an opening (21) bounded by a cutting edge (16); a helical knife (17) coupled to the outer member for rotation relative to the outer member. The helical knife (17) has an edge to slide into tissue to draw the tissue proximally along the helical knife towards the cutting edge.

Regarding claims 26-27, wherein the edge of helical knife (17) extends distally through the opening (21); and where the cutting edge and the edge of helical knife (fig. 1) configure to cut tissue.

Regarding claims 33-34 and 50-51, where the device further includes a hub (13), where the outer member (20) defines a fluid. The cutting edge (16) is located at a distal end of the outer member. The outer member tapers to the cutting edge (fig. 1).

Regarding claims 18-24 and 60, Baehr is capable of performing the method steps as claimed in fig. 1, col. 2, lines 48-54, col. 3, lines 1-7 and col. 4, lines 29-32.

Claims 18,25,31,36-42,47 and 53-60 are rejected under 35 U.S.C. 102(b) as being anticipated by Kerfoot, Jr (U.S. 3,976,077).

Kerfoot et al disclose in figs. 2-3, a surgical cutting instrument having the limitations of the above listed claims, including: a cutting instrument (20); an outer member (24) has an opening (26) bounded by a cutting edge (the cutting edge is considered at the tip of segment 24 in fig. 2); a helical knife (30) coupled to the outer member for rotation relative to the outer member. The helical knife (30) has an edge to slide into tissue to draw the tissue proximally along the helical knife towards the cutting edge.

Regarding claims 31-32 and 46-48, wherein the edge of the helical knife (30) includes a helical channel (see the arrow sign in fig. 3); wherein the helical channel has a pitch that increases from the distal end to the proximal end; and wherein the helical channel terminates in an opening through a wall of the inner member (42).

Regarding claims 36-42 and 52-58, wherein the cutting edge is part circumferential, circular or oblong in shape; and wherein the outer member includes a shield portion (fig. 2).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baehr et al (U.S. 3,906,954).

Baehr et al are explained as before. Although, Baehr et al do not disclose the inner member and the outer member is in the range of about 0.0005 to 0.002 inches. It would have been obvious matter of design choice to modify the inner member and the outer member is in the range of about 0.0005 to 0.002 inches, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re-Aller, 105 USPQ 233.

Conclusion

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Pat. No. 3,614,953 to Moss

U.S. Pat. No. 3,937,222 to Banko

U.S. Pat. No. 4,649,919 to Thimsen

Art Unit: 3731

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor X Nguyen whose telephone number is (703) 305-4898. The examiner can normally be reached on M-F (8-4.30 P.M.).

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Victor X Nguyen
Examiner
Art Unit 3731

Vn *VW*
10/21/2004



JULIAN W. WOO
PRIMARY EXAMINER